MAY - 2 2000

K000665

TFX Medical

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
TFX Medical Group
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
Facsimile: (603) 532-6207

Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Catheter Introducer

Common Name: Safety Needle with Split Sheath Catheter Introducer

Proprietary Name: TFX Medical Safety Needle with Introducer

3. Identification of the legally marketed device to which the submitter claims equivalence:

The TFX Medical Safety Needle with Introducer is substantially equivalent to the:

Catheter Introducer in the Johnson and Johnson Medical, Inc. IV Catheter System, K980493.

PUNCTUR-GUARD Blood Collection Needle of Bio-Plexus, Inc, for the activation mechanism, K895024

TFX Medical, Inc. Over-the-Needle Splitable Catheter Assembly, Type I, K920908

Daig Corporation Stix™ Needle/Peel-Away Catheter Introducer

4. Description of the Device.

The TFX Medical Safety Needle with Introducer consists of a passively activated safety needle over which is positioned a peelable split sheath introducer. These members are sold integrally paired. Over the assembly is a needle cover, which protects the device during processing, shipping and storage and prior to insertion into the body. There is no sharps protection until the device has been activated during needle withdrawal.

5. Intended Use of the Device.

The product is used to provide vascular access for the introduction of devices.

The TFX Medical Safety Needle with Introducer assembly is two-part. The first part is equipped with a hollow stainless steel needle, which contains the passively activated internal blunting mechanism, which is activated by the blunter advancing beyond the tip of the needle, thus reducing the risk of accidental needle stick injury. The blunting mechanism is activated upon withdrawal from the hub of the peelable split sheath introducer, which forms the second part of the assembly.

6. Summary of Technological Characteristics.

The device is equivalent technologically to the devices mentioned on page 1. The anti-stick safety feature, which forms an integral part of this device, is the reason for this submission. This feature is an integral part of the Johnson and Johnson Safety Needle, part of the Johnson and Johnson I.V. Catheter System and the Bio-Plexus Punctur-Guard® Blood Collection Needle. In both of these devices, the safety feature includes a self-blunting needle, which locks in place, once passive activation takes place.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 – 2000

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
TFX Medical, Incorporated
Tall Pines Park
Jaffrey, New Hampshire 03452

Re: K000665
Trade Name: TFX Medical Safety Needle with Introducer
Regulatory Class: II
Product Code: FOZ
Dated: February 25, 2000
Received: February 28, 2000

Dear Ms. Brozowski:

This letter corrects our substantially equivalent letter of May 2, 2000, regarding the Indication for Use Statement.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000665

Device Name: TFX Medical Safety Needle with Introducer

Indications For Use:

This product is used to provide vascular access for the introduction of catheters.

The TFX Medical Safety Needle with Introducer assembly is two-part. The first part is equipped with a hollow stainless steel needle, which contains the passively activated internal blunting mechanism, which is activated by the blunter advancing beyond the tip of the needle, thus reducing the risk of accidental needle stick injury. The blunting mechanism is activated upon withdrawal from the hub of the peelable split sheath introducer, which forms the second part of the assembly.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000665

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)